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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,892	07/09/2001	Stephen Carl McKeown	PG3576USW	7728

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER

1627

DATE MAILED: 09/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,892

Applicant(s)

McKeown et al

Examiner

Maurle G. Bak r, Ph.D.

Art Unit

1627

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Preliminary Amendment

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-37 is/are pending in the application

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-37 are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. The Preliminary Amendment is noted. Claims 6, 12-14, 17, 20-22, 24-29, 31-34 and 36 were amended and no claims were cancelled or added. Therefore, claims 1-37 are currently under consideration.

#### *Election/Restriction*

2. It is noted that the instant claims are extremely confusing and many have incorrect (or confusing) dependencies. For the purposes of this Restriction Requirement, it has been assumed that the group A is the same as the group G and that they are part of the broader group Fr. The relationships of many of the other variables are also unclear and this will be addressed further when the case is examined on the merits. Note that due to inconsistencies in the claims, further restriction and/or election may be necessary upon any amendment to the claims. Also note the additional *election of species requirement* set forth in paragraphs 10-14.

3. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention from the following groups to which the claims must be restricted.

- I. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *first* formula shown in claim 25.
- II. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *second* formula shown in claim 25.
- III. Claims 1-5, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *third* formula shown in claim 25.
- IV. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *fourth* formula shown in claim 25.
- V. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part) and claim 26, drawn to a “chemical construct” depicted by the *fifth* formula shown in claim 25.
- VI. Claims 1-5, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *sixth* formula shown in claim 25.
- VII. Claims 1-5, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *seventh* formula shown in claim 25.
- VIII. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *eighth* formula shown in claim 25.
- IX. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *ninth* formula shown in claim 25.
- X. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *tenth* formula shown in claim 25.

- XI. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *eleventh* formula shown in claim 25.
- XII. Claims 1-5, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *twelfth* formula shown in claim 25.
- XIII. Claims 1-5, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *thirteenth* formula shown in claim 25.
- XIV. Claims 1-5, 6, 7, 13-18, 20-25 and 27 (all in part), drawn to a “chemical construct” depicted by the *fourteenth* formula shown in claim 25.
- XV. Claims 1, 6, 7, 13 and 17-24 (all in part) and claims 8-11, drawn to a “chemical construct” that has Y<sup>a</sup> (and F<sup>a</sup>) moieties.
- XVI. Claims 1, 13 and 17-24 (all in part) and claim 12, drawn to a “chemical construct” that has Y<sup>b</sup> (and F<sup>b</sup>) moieties.
- XVII. Claims 28-31 (all in part), drawn to an “intermediate construct” depicted by the *first* formula shown in claim 29.
- XVIII. Claims 28-31 (all in part), drawn to an “intermediate construct” depicted by the *second* formula shown in claim 29.
- XIX. Claims 28-31 (all in part), drawn to an “intermediate construct” depicted by the *third* formula shown in claim 29.
- XX. Claims 28-31 (all in part), drawn to an “intermediate construct” depicted by the *fourth* formula shown in claim 29.
- XXI. Claims 28, 29 and 31 (all in part), drawn to an “intermediate construct” depicted by the *fifth* formula shown in claim 29.
- XXII. Claims 28, 29 and 31 (all in part), drawn to an “intermediate construct” depicted by the *sixth* formula shown in claim 29.
- XXIII. Claim 32, drawn to a differential release method.
- XXIV. Claim 33, drawn to a tiered release method.
- XXV. Claim 34 and 35, drawn to a method of determining the identity of a substrate.
- XXVI. Claim 36 and 37, drawn to a method of identifying a pharmaceutically useful substrate.

5. The inventions listed as Groups I – XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

6. The technical feature that links all of the claims is the claimed “chemical construct”. The groups lack unity because the claimed “chemical constructs” are known in the art as disclosed by Lebl et al (US 5,840,485) or Lebl et al (US 5,635,598). These references are described below.

7. Lebl et al (US 5,840,485) disclose solid phase supports having a variety of differently cleavable linkers attached thereto. See, for example, Figures 1A, 1B, 2A-C and 3 of the patent. Specifically, Lebl et al (‘485) disclose several different set-ups of solid support, linkers, library component and coding tags (see columns 37-44) that read on the claimed “constructs”. The structure of such entities is shown in Schemes XIA, XIB and XIC of the reference (columns 41-44). The use of specific coding moieties that are able to be differentially cleaved and read by mass spectroscopy is described in column 40, line 65 through column 41, line 4. See also Section 7.2.1 beginning in column 54 and Section 13.2.2 beginning in column 85. Lebl et al (US 5,635,598) disclose solid phase supports having a variety of differently cleavable linkers attached thereto. See, for example, patented claims 1, 4, 6, 12, 16, 18 & 20-47. Lebl et al (‘598) disclose “multiply cleavable linkers, in which cleavage of each linker is independent of the cleavage of the others” (column 3, lines 9-15). Specifically, Figure 8 shows a set-up

where three differently cleavable sites are shown, as well as a fourth site with a coding tag.

8. Also, each of the products of Groups I – XXII have a *different chemical structure* and their modes of action and chemical reactivity would be different. Thus, they each represent separate and distinct products (having different inventive concepts). They differ in respect to their properties, the synthetic methodology for making them and/or their use. The methods of Groups XXIII – XXVI also represent different inventive concepts as they represent different methods, with different steps, different reagents and/or different end results.

9. Moreover, note the following regarding the relationship between intermediates and final products when determining unity of invention (from MPEP 1850): “If the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.”

10. This application contains claims directed to more than one species of the generic invention for *all of Groups I – XXVI*. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 (see below).

11. If applicant elects the invention of any of **Groups I – XVI**, applicant is required to elect from the following patentably distinct species.

Type of “chemical construct”

Applicant is required to elect, for purposes of search, *a single, specific structure* of the claimed “chemical construct”. This structure should have all variables defined down to the level of atoms and bonds, i.e. be completely defined as a single structure. The claims readable on the elected species should also be indicated (see paragraph 15 below).

12. If applicant elects the invention of any of **Groups XVII – XXII**, applicant is required to elect from the following patentably distinct species.

Type of “intermediate construct”

Applicant is required to elect, for purposes of search, *a single, specific structure* of the claimed “intermediate construct”. This structure should have all variables defined down to the level of atoms and bonds, i.e. be completely defined as a single structure. The claims readable on the elected species should also be indicated (see paragraph 15 below).

13. If applicant elects the invention of any of **Groups XXIII – XXVI**, applicant is required to elect from the following patentably distinct species.

Type of “chemical construct” used in the method

Applicant is required to elect, for purposes of search, *a single, specific structure* of the “chemical construct” that is used in the claimed method. This structure should have all variables defined down to the level of atoms and bonds, i.e. be completely defined as a single structure. The claims readable on the elected species should also be indicated (see paragraph 15 below).

14. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions



involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". As the claimed "chemical constructs" are known in the art (see paragraphs 6-7 above), election under these rules is proper and required.

15. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is

complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone

number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
September 6, 2002

A handwritten signature in black ink, consisting of stylized initials 'MB' followed by a long horizontal flourish.

**MAURIE GARCIA BAKER, Ph.D.  
PATENT EXAMINER**